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The impact of hand hygiene technique on hand hygiene compliance and microbiological efficacy

Submission date
02/05/2018

Recruitment status
No longer recruiting

Registration date
09/05/2018

Overall study status
Completed

Last Edited
17/06/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hand hygiene is one of the most important measures to prevent spread of disease causing organisms (pathogens) in healthcare settings and ultimately, healthcare-associated infections. Despite multiple strategies to increase compliance with hand hygiene, compliance remains insufficient at most institutions, especially when considering that a 10%-improvement in hand hygiene compliance results in a 6%-reduction in healthcare-associated infections and that decreases in infection rates have been demonstrated even when improving hand hygiene compliance rates from high (>80%) to very high (>95%).The technique for the use of hand rub outlined in the WHO guidelines consists of six steps to ensure entire coverage of the hands. If several areas of the hands are frequently missed when applying hand rub, this may potentially limit effectiveness of hand hygiene performance and overall compliance of healthcare workers with all six steps is low.
We previously proved that a hand hygiene technique consisting of three steps fulfils the European Standard (EN 1500) norm and is even slightly superior regarding reduction of the bacteria when compared to the technique consisting of six steps. However, results from such an experimental study may not be the same in clinical settings. This study therefore compares compliance of healthcare workers to both hand hygiene techniques, as well as reduction of the bacterial load on the hands of healthcare workers between the three and six step hand hygiene techniques.

Who can participate?
All healthcare workers on participating wards

What does the study involve?
Healthcare workers are observed and their compliance with hand hygiene technique and indications are assessed. Furthermore effectiveness of both hand hygiene techniques at removing bacteria is determined by assessing bacterial counts before and after use of hand rub.
What are the possible benefits and risks of participating?
There were no risks or benefits for participants of this study.

Where is the study run from?
University Hospital Basel (Switzerland)

When is the study starting and how long is it expected to run for?
August 2015 to December 2017

Who is funding the study?
University Hospital Basel (Switzerland)

Who is the main contact?
Dr Sarah Tschudin Sutter (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Tschudin Sutter

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Handhygiene10/2015

Study information

Scientific Title
Simplifying the WHO protocol: Three steps versus six steps for performance of hand hygiene - a cluster-randomized trial

Study objectives
We previously proved that a hand hygiene technique consisting of three steps fulfills the EN 1500 norm and is even slightly superior regarding reduction of the
bacterial load as compared to the technique consisting in six steps. However, results from such an experimental study may not extrapolate to clinical settings.
We therefore compare compliance with both hand hygiene technique and indications, as well as reduction of the bacterial load on the hands of healthcare workers between the hand hygiene techniques consisting of three and six steps for use of hand rub.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not required: this study is part of our quality assurance program.

Study design
Cluster-randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
As no patients were included in this study, there is no participant information sheet available.

Health condition(s) or problem(s) studied
Prevention of healthcare-associated infections and transmission of pathogens in healthcare settings.

Interventions
Twelve wards are randomly assigned to either the 3-step technique or the conventional 6-step technique for use of hand rub.
The following two hand hygiene techniques outlining the steps for application of hand rub are compared in this trial:
The 6-step technique as recommended by the WHO (Organization WHO. WHO Guidelines on Hand Hygiene in Health Care, First Global Patient Safety Challenge Clean Care is Safer Care 2009) and the 3-step technique as previously reported (Tschudin-Sutter S, Rotter ML, Frei R, et al. Simplifying the WHO 'how to hand rub' technique: three steps are as effective as six-results from an experimental randomized crossover trial. Clin Microbiol Infect 2017).
The 3-step technique consists of: (1) covering all surfaces of the hands (based on own judgement), (2) rotational rubbing of fingertips in the palm of the alternate hand, and (3), rotational rubbing of both thumbs.
The 6-step technique: (1) rubbing hands palm to palm, (2) palm to palm with fingers interlaced, (3) right palm over left dorsum with interlaced fingers and vice versa, (4) back of fingers to opposing palms with fingers interlocked, (5) rotational rubbing of left thumb clasped in right palm and vice versa, and (6) rotational rubbing backwards and forwards with clasped fingers of right hand in left palm and vice versa.
Both techniques are performed for 30 seconds using three ml of hand rub.
Educational activities outlining the importance of hand hygiene, compliance to the five hand hygiene indications as outlined by the WHO and technique are provided to all participating wards. These consist of tutorials taught by experienced infection control nurses prior to trial

initiation and weekly thereafter. Pocketcards outlining both hand hygiene technique and the five indications are distributed to all healthcare workers of the participating wards. The content of the educational tutorial as well as videos demonstrating all steps of the two hand hygiene techniques compared in this trial are made accessible over our institutions intranet.

Hand hygiene observations
Direct hand hygiene observations are performed to assess both compliance to the assigned hand hygiene technique, as well as to hand hygiene indications. All hand hygiene observations are performed by four trained observers throughout the study period using an electronic case report form. The following information is captured: Compliance to the five hand hygiene indications (i.e., (1) before touching a patient, (2) after touching a patient, (3) after touching patient surroundings, (4) after body fluid exposure risk, and (5) before clean/aseptic procedure"), compliance to each individual step of the assigned hand hygiene technique (i.e. 3 step or 6-step technique,

Microbiological assessments
Healthcare workers of all participating wards are randomly approached during their routine daily activities for assessments of bacterial counts on their hands prior and after use of hand rub. The European norm (EN 1500) is the reference standard for bacterial count assessment and statistical analyses, with a few modifications, the most important one being that no artificial contamination with Escherichia coli isperformed (1500 ECfSEN. Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2) 2013).Bacterial counts are assessed by immersing the dominant hand in a sterile plastic bag containing 100ml of tryptic soy broth (TSB) and kneading the dominant hand for one minute. Solutions will be then plated onto tryptic-soy-agar plates and incubated for 24 and 48 hours at 36°C before the number of CFUs is assessed. We chose to use 100ml of TSB rather than 10ml of TSB as outlined in the EN 1500 to obtain a representative measurement of the number of
colony forming units (CFUs) on the entire surface of hands rather than just the fingertips. The hand rub used at our institutions is Sterillium®classic pure (Paul Hartmann AG, Heidenheim, Germany), which in addition to the alcoholic compounds (propan-2-ol 45.0 g, propan-1-ol 30.0 g per 100g, respectively) also contains mecetroniumetilsulfat (0.2 g per 100g), which has a sustained effect, therefore, a neutralizing agent (containing polysorbate, saponin, histidine und cysteine, as outlined by the EN 15009) will be added to the TSB solution.

Intervention Type
Other

Primary outcome measure
1. Compliance with the assigned technique is assessed using direct observations by four trained observers using an electronic case report form at random throughout the study period
2. Bacterial counts on hands of healthcare workers are measured using EN 1500 bacterial count assessment, at random throughout their routine daily activities in the study period

Secondary outcome measures
Compliance with the five hand hygiene indications as outlined by the WHO is assessed using direct hand hygiene observations by four trained observers using an electronic case report form throughout the study period

Overall study start date
01/08/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
All handhygiene actions performed on included wards were eligible for inclusion.

Participant type(s)
Health professional

Age group
All

Sex
Both

Target number of participants
A priori power calculations were performed to determine sample sizes for both primary endpoints. Power calculation of the sample size required to detect a meaningful difference in compliance depending on hand hygiene technique were based on the assumption of compliance being 9% for the 6-step technique and 20% for the 3-step technique. Assuming superiority, a two-sided significance level of 0.05 and power of 0.9, 274 observations of hand hygiene opportunities need to be performed. Assuming non-inferiority, a one-sided significance level of 0.025, power of 0.9, and a margin of inferiority of 0.6 log units, 37 measurements of pre-and post-values were needed to demonstrate equivalence of both techniques in terms of reduction in bacterial counts after performance of hand hygiene.

Key exclusion criteria
Bacterial count (measured in number of colony forming units) prior to hand rub use was less than a mean of 5log CFU.

Date of first enrolment
01/10/2015

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Petersgraben 4

Basel
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Sponsor information

Organisation
Division of Infectious Diseases & Hospital Epidemiology, University Hospital Basel

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Division of Infectious Diseases & Hospital Epidemiology, University Hospital Basel

Results and Publications

Publication and dissemination plan
We plan to publish our results in a peer reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sarah Tschudin-Sutter (sarah.tschudin@usb.ch)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		29/01/2019	29/01/2019	No	No
Results article	results	01/08/2019	17/06/2020	Yes	No